



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

May 4, 2004

Nicholas M. Fleischer, R.Ph., Ph.D.
Vice President, Clinical Pharmacology & Biopharmaceutics
The Weinberg Group Inc.
1220 Nineteenth Street, N.W., Suite 300
Washington, DC 20036-2400

Dear Dr. Fleischer:

Your petition requesting the Food and Drug Administration to declare that the drug product, Glyburide and Metformin HCl Tablets for Oral Suspension, 1.25 mg/250 mg; 2.5 mg/500 mg; 5 mg/500 mg, is suitable for submission as an abbreviated new drug application, was received by this office on 05/03/2004. It was assigned docket number 2004P-0209 and it was filed on 05/04/2004. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

